

Pregozen (U.S. Patent No. 5,141,803), and Jorgensen (EP 1 055 424). Applicant respectfully traverses this rejection.

The Examiner relies on Singh for the teaching of a pharmaceutical composition for treating anorectal and colonic diseases which can be formulated in the form of a foam, medicated pads, etc. The Examiner notes Singh's description of the use of one or more aqueous and nonaqueous solvents, surfactants and stabilizing agents. However, the Examiner notes that Singh fails to teach a specific formulation of a foaming composition.

The Examiner relies on Fowler for the teaching of personal cleansing foams in a manually actuated pump. The Examiner notes Fowler's description of a foaming composition comprising 35-99.65% water, 0.1-20% surfactants, and 0.1-25% humectants, as well as the optional inclusion of certain active ingredients. The Examiner further notes that Fowler teaches the use of sponges or washcloths. However, the Examiner notes that Fowler fails to teach a specific combination of surfactants.

The Examiner relies on Pregozen for its alleged teaching of the key ingredients used in personal hygiene wipe products, such as cocoamphodiacetate and polysorbate 20. The Examiner relies on Jorgensen for its alleged teaching of a mild aqueous foamable skin cleanser comprising triethanolamine cocoyl glutamate as a preferred foaming agent, glycerin and water.

Finally, the Examiner maintains that it would have been obvious to provide a foaming product along with a conventional substrate to apply the foaming product as a lather-forming device and for convenience to users as suggested by Fowler and Pregozen; the Examiner further maintains that the claimed bathroom tissue is rendered obvious by

Pregozen's teaching of a disposable, fibrous substrate. Applicant respectfully disagrees with the Examiner's interpretations of the cited art and submit that the present invention, as set forth in claims 26-30, is not rendered obvious by the cited art.

Independent claim 26 ("wipe product") is directed to a vaginal or hemorrhoidal wipe product comprising a stable foam disposed on bathroom tissue. Independent claim 27 ("foam wipe kit") is directed to a foam wipe kit comprising a propellantless finger actuated mechanical pump dispenser containing a propellant-free foamable aqueous composition capable of forming a stable foam on dispensing and a disposable substrate. Independent claim 28 ("foamable aqueous composition") is directed to a propellant-free foamable aqueous composition capable of forming a stable foam suitable for use as a vaginal or hemorrhoidal wipe comprising water, a surfactant combination of polysorbate 20, triethanolamine cocoyl glutamate and disodium cocoamphodiacetate, and a foam stabilizing agent.

While Singh is directed to pharmaceutical compositions used with anorectal and colonic diseases, it fails to render obvious any of the presently claimed wipe product, foam wipe kit and foamable aqueous composition. In addition to Singh's complete failure to give a foaming composition formulation (as noted by the Examiner), Singh provides no guidance whatsoever in terms of the formulation of a stable foam as is critical to the present invention. In fact, Singh fails to appreciate that various foam characteristics can be had at all and therefore provides no guidance with respect to stable foam formulating considerations. Lending credence to the fact that Singh provides no meaningful disclosure with respect to foams is Singh's apparent equation between foam and spray bases. (See Singh, column 5, line 11.) What is more, Singh fails to disclose or suggest either of the

disposable substrate, e.g., bathroom tissue, and the pump dispenser; Singh's disclosure of medicated pads is irrelevant as such are wholly different from the substrate of the present invention. Clearly, Singh alone does not render obvious the invention of claims 26-30.

Fowler does not remedy Singh's deficiencies. Not unlike Singh, Fowler fails to disclose or suggest the disposable substrate, e.g., bathroom tissue, of the present invention; clearly, Fowler's suggested sponge or washcloth is not a disposable substrate as is used in the present invention. While Fowler does describe a foam producing cleansing product containing water, surfactants, etc., Fowler fails to disclose or suggest a convenient foam producing cleansing product of the type used in the present invention. In pertinent part, Fowler sets forth:

The personal cleansing products of the present invention are useful for cleansing the skin or hair. Typically, a suitable amount of the cleansing composition is directly applied as a foam from the non-aerosol [pump] to the skin or hair to be cleansed. It is preferred to premoisten the skin or hair with water. Alternatively, a suitable amount of the cleansing composition can be applied to the skin or hair to be cleaned via intermediate application to the hands, a washcloth, a sponge, or other application device. It has been found that the compositions of the present [invention] provide their optimal cleansing performance when combined with water during the cleansing process. To complete the cleansing process, the compositions of the instant invention are thoroughly rinsed from the skin or hair with water. (Column 33, line 66, through column 34, line 12.)

It is abundantly clear that the foaming composition of Fowler is not analogous to the stable foam used in the present invention. First, the foam of Fowler is ideally used with water and must be thoroughly rinsed off the skin and hair to complete the cleansing process. The stable foam used in the invention of claims 26-30 need not be combined with water at any point in the application and/or removal processes. Instead, the present invention is intended to provide a convenient solution to the problems associated with conventional

surfactant
provided in
Fowler
Drs

products such as that proposed by Fowler. The stable foam of the present invention can be used simply by dispensing the foam onto a piece of bathroom tissue, applying the foam to the vaginal or anal area, i.e., "wiping", and removing any excess foam with the bathroom tissue.

Second, Fowler is concerned only with cleansing hair and skin; hair and skin are very different from the mucosal vaginal and anal areas to which the presently employed stable foam is to be applied. → Proj Applicant submits that the recitation of "vaginal or hemorrhoidal" or "suitable for use as a vaginal or hemorrhoidal wipe" in the preambles of claims 26-28 is not merely a statement reciting purpose or intended use; instead it serves to further define the product set forth in the body of the claim and is "necessary to give life, meaning and vitality" to the claims. Pitney Bowes, Inc. V. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999). As such, these phrases should be given due consideration. Further, specific formulation considerations must be made when formulating a vaginal or hemorrhoidal wipe product. For instance, particular surfactant blends can be critical. As noted by the Examiner, Fowler provides no guidance at all with respect to the particular surfactant blend set forth in claim 28. For all of the above reasons, Fowler whether considered alone or in combination with Singh fails to render the present invention obvious.

Pregozen fails to remedy the deficiencies of Singh and Fowler. As noted in the previous response, Pregozen relates to moistened or impregnated nonwoven substrates. ND Quite distinctly, the present invention relates to the use of disposable substrates such as hbn
5 ft
1 ft bathroom tissue. As outlined in detail at, inter alia, page 5 of the present specification, the integrity of the bathroom tissue or disposable substrate is not compromised, i.e., there is no

absorption or impregnation, according to the present invention. While Pregozen may describe the use of disodium cocoamphodiacetate and polysorbate 20 in its disposable hygiene wipes, Pregozen is not in any way directed to the formulation of stable foams nor the dispensation of such stable foams on a disposable substrate. Because Pregozen is completely unrelated to foam products, the combination of Pregozen and Fowler is inappropriate; Pregozen relates to personal hygiene wipes, while Fowler relates to foaming hair and skin cleansers. In any event, Pregozen fails to aid Singh and Fowler in rendering obvious the invention of present claims 26-30.

that's
H

Finally, Jorgensen does not remedy the deficiencies of the above-discussed cited art. Jorgensen is cited merely for its alleged teaching of triethanolamine cocoyl glutamate as a preferred foaming agent in a foamable skin cleanser. Jorgensen, like Fowler, is directed to a skin cleanser, as opposed to a vaginal or hemorrhoidal agent as in the present invention. In addition, Jorgensen contains no disclosure or suggestion of the application of its foamable skin cleanser to a disposable substrate; likewise, there is no indication that its foamable skin cleanser would be suitable for such a purpose. Clearly, Jorgensen, even in combination with the other cited references, fails to render the present invention obvious.

In sum, no combination of Singh, Fowler, Pregozen and Jorgensen can be said to render the invention of present claims 26-30 obvious. First, Applicant does not believe that one of ordinary skill in this art would combine these references. They relate to different types of products, and at least three of the four cited references have required elements. Singh requires the presence of a flavanoid-containing *Euphorbia prostate* extract as an active ingredient; Fowler necessarily includes a water soluble cationic or

non
analogous

nonionic polymer to aid in the deposition of humectants and/or emollients; and Jorgensen requires the inclusion of a salt of acrylates/ C_{10-30} alkyl acrylate crosspolymer or a salt of acrylates polymer as a foam stabilizer. Certainly no combination of such elements renders the present invention obvious.

Second, the cited references fail to disclose or suggest key features of present claims 26-30, namely a stable foam, a disposable substrate and particular surfactants, all for use in vaginal or hemorrhoidal wipe products. The present invention, quite simply, is directed to the application of a highly aqueous foam on a very low wet strength disposable substrate such as bathroom tissue; the foam is so designed so as to retain its integrity such that it does not moisten the disposable substrate and collapses only when applied to the vaginal or anal area. All of the medicated pads of Singh, sponge and washcloth of Fowler and moistened or impregnated substrates of Pregozen are fundamentally distinguishable from the low wet strength disposable substrates suitable for use in the present invention. In fact, no foam which could be suggested from any combination of the above-discussed references would be suitable for use with the substrates used in the present invention.

Accordingly, Applicant respectfully requests withdrawal of the §103 rejection premised upon the combination of Singh, Fowler, Pregozen and Jorgensen.

Claims 1, 3, 4, 7, 13, 17-21 and 23-25 stand rejected under 35 U.S.C. §103(a) as being obvious over Vinski (U.S. Patent No. 6,030,931). Claims 8-10 stand rejected under 35 U.S.C. §103(a) as being obvious over Vinski and further in view of Pregozen and Jorgensen. Claims 14-16 stand rejected under 35 U.S.C. §103(a) as being obvious over Vinski, Pregozen and Jorgensen and further in view of Mohseni (U.S. Patent

No. 5,431,906), Evans (U.S. Patent No. 5,837,661) and Wenninger (Int'l Cosmetic Ingredient Dictionary and Handbook). Applicant respectfully traverses these rejections.

The Examiner relies on Vinski for the teaching of a non-aerosol foaming skin cleansing product comprising an anionic surfactant, an amphoteric surfactant and water; the Examiner also notes that Vinski describes the use of emollients, preservatives, vitamins, colors and fragrances. The Examiner alleges that it would have been obvious for one of ordinary skill in the art to discover optimum or workable ranges of the components of a foam cleanser through routine experimentation.

The Examiner applies Pregozen and Jorgensen in the same manner as above. Further, the Examiner relies on Mohseni, Evans and Wenninger merely for their disclosures related to PEG 23M and xanthan gum as thickeners in cleansing formulations. Applicant respectfully disagrees with the Examiner's interpretations of the cited art and submit that the present invention, as set forth in claims 1, 3, 4, 7-10, 13-19 and 22-25, is not rendered obvious by the cited art.

Independent claims 1, 21 and 23 are directed to propellant-free foamable aqueous compositions which are capable of forming a stable foam when dispensed from a propellantless finger actuated mechanical pump dispenser and which are suitable for use as a vaginal or hemorrhoidal wipe. Importantly, each of the claimed aqueous compositions contain (a) water in an amount from about 70% to about 98% by weight, based on the total weight of the aqueous composition; (b) surfactant in an amount from about 2% to about 35% by weight, based on the total weight of the aqueous composition, wherein the surfactant is selected from the group consisting of nonionic surfactants, amphoteric surfactants, anionic surfactants and mixtures thereof; and (c) foam stabilizing agent in an

amount from about 0.10% to about 5% by weight, based on the total weight of the aqueous composition, wherein the foam stabilizing agent is selected from the group consisting of natural and synthetic gums, polyalkylene glycols, alkylene polyols and combinations thereof. Independent claim 21 further includes a medicament. Newly independent claim 23 further includes a lubricant, chelating agent, moisturizer, healing agent, fragrance, color or mixture thereof. All three of these independent claims use “consisting essentially of” language.

The presently claimed invention is distinct from the cited art. First, the foamable aqueous compositions of this invention are suitable for use as a vaginal or hemorrhoidal wipe. Contrary to the Examiner’s position and as noted above, Applicant submits that the recitation of “suitable for use as a vaginal or hemorrhoidal wipe” in the preambles of claims 1, 21 and 23 is not merely a statement reciting purpose or intended use; instead it serves to further define the product set forth in the body of the claim and is “necessary to give life, meaning and vitality” to the claims. Pitney Bowes, Inc. V. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999). As such, the phrase should be given patentable weight. Not every combination of water, surfactant and foam stabilizer would be suitable for use as a vaginal or hemorrhoidal wipe; specific formulation considerations must be made. Vinski, which is directed to a skin cleansing skin product, does not make such considerations.

Second, Vinski necessarily includes two specific foam densifying agents, namely a C₈₋₁₂ acyl lactylate and an ethoxylated glyceride ester. The foamable aqueous compositions of the present invention, which produce what can be described as light, quick-breaking foams, do not include such densifying agents and, in fact, are closed to the

possibility of such an inclusion given the “consisting essentially of” language. The foam densifying agents are indispensable to the foaming skin cleanser of Vinski as Vinski aims to produce a “rich, luxurious creamy foam” (column 2, lines 16-17). In Examples 9-18 thereof, only foams which comprised the claimed C₈₋₁₂ acyl lactylate and ethoxylated glyceride ester (Examples 15-18) were deemed completely satisfactory; examples which merely employed an amphoteric surfactant or an anionic surfactant or a combination of the two were deemed deficient in at least some respect. From the disclosure of Vinski, it is clear that the combination of C₈₋₁₂ acyl lactylate and ethoxylated glyceride ester materially affects the overall foam characteristics.

None of the cited secondary references remedy the deficiencies of Vinski; none provide any motivation to prepare stable foams suitable for use as a vaginal or hemorrhoidal wipe, nor do any provide any motivation to alter the composition of Vinski to remove vital components, i.e., C₈₋₁₂ acyl lactylate and ethoxylated glyceride ester, thereof. What is more, Pregozen and Jorgensen have additional deficiencies as discussed above, and Mohseni, Evans and Wenninger are cited merely to prove the efficacy of PEG 23M and xanthan gum as suitable thickeners.

In sum, no combination of Vinski, Pregozen, Jorgensen, Mohseni, Evans and Wenninger can be said to render the invention of present claims 1, 3, 4, 7-10, 13-19 and 22-25 obvious. First, Applicant believes that there are issues which would preclude the combination of at least some of these references. For instance, Vinski necessarily requires the presence of C₈₋₁₂ acyl lactylate and ethoxylated glyceride ester as foam densifying agents, while Jorgensen requires the inclusion of a salt of acrylates/C₁₀₋₃₀ alkyl acrylate crosspolymer or a salt of acrylates polymer as a foam stabilizer. Certainly no

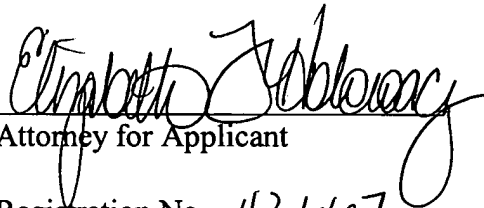
combination of such elements renders the present invention obvious. Second, the cited references fail to disclose or suggest the invention of present claims 1, 3, 4, 7-10, 13-19 and 22-25, namely they fail to disclose or suggest a propellant-free foamable aqueous composition capable of forming a stable foam suitable for use as a vaginal or hemorrhoidal wipe consisting essentially of the claimed amounts of water, specified surfactants and specified foam stabilizing agents. Accordingly, Applicant respectfully requests withdrawal of the §103 rejections premised upon Vinski, Pregozen, Jorgensen, Mohseni, Evans and Wenninger alone and/or in combination.

Claims 21 and 22 stand rejected under 35 U.S.C. §103(a) as being obvious over Singh in view of Vinski. Applicant respectfully traverses this rejection. For all of the reasons set forth above with regard to both Singh and Vinski, Applicant maintains that the invention of claims 21 and 22 is not obvious and that a combination of Singh and Vinski is unlikely given Singh's required flavanoid-containing *Euphorbia prostate* extract and Vinski's required C₈₋₁₂ acyl lactylate and ethoxylated glyceride ester. Accordingly, Applicant respectfully requests withdrawal of this §103 rejection.

This Amendment After Final Rejection is believed clearly to place this application in condition for allowance. Its entry is therefore believed proper under 37 C.F.R. §1.116. Accordingly, entry of this Amendment After Final Rejection, as an earnest attempt to advance prosecution, is respectfully requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicant's undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,


Attorney for Applicant
Registration No. 42,1667

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200



VERSION SHOWING CHANGES MADE TO CLAIMS

8. (Twice Amended) The propellant-free foamable aqueous composition according to claim 1, wherein the surfactant is a combination of polysorbate 20, [triethylamine] triethanolamine-cocoyl glutamate and disodium cocoamphodiacetate.

9. (Amended) The propellant-free foamable aqueous composition according to claim 8, wherein polysorbate 20 is present in an amount from about 0.1% to about 2%, [triethylamine] triethanolamine-cocoyl glutamate is present in an amount from about 1% to about 15%, and disodium cocoamphodiacetate is present in an amount from about 1% to about 15% by weight, based on the total weight of the aqueous composition.

10. (Amended) The propellant-free foamable aqueous composition according to claim 9, wherein polysorbate 20 is present in an amount of about 1%, [triethylamine] triethanolamine-cocoyl glutamate is present in an amount of about 5%, and disodium cocoamphodiacetate is present in an amount of about 5% by weight, based on the total weight of the aqueous composition.

23. (Twice Amended) [The] A propellant-free foamable aqueous composition [according to claim 1 further consisting of] capable of forming a stable foam when dispensed from a propellantless finger actuated mechanical pump dispenser and suitable for use as a vaginal or hemorrhoidal wipe consisting essentially of:

(a) water in an amount from about 70% to about 98% by weight, based on the total weight of the aqueous composition;

(b) surfactant in an amount from about 2% to about 35% by weight, based on the total weight of the aqueous composition, wherein the surfactant is selected from the group consisting of nonionic surfactants, amphoteric surfactants, anionic surfactants and mixtures thereof;

(c) foam stabilizing agent in an amount from about 0.10% to about 5% by weight, based on the total weight of the aqueous composition, wherein the foam stabilizing agent is selected from the group consisting of natural and synthetic gums, polyalkylene glycols, alkylene polyols and combinations thereof; and

(d) a constituent selected from the group consisting of lubricants, chelating agents, moisturizers, healing agents, fragrance, color and mixtures thereof.

27. A vaginal or hemorrhoidal foam wipe kit comprising:

(a) a propellantless finger actuated mechanical pump dispenser containing a propellant-free foamable aqueous composition capable of forming a stable foam on dispensing; and

(b) a disposable substrate for receiving the stable foam.

28. (Amended) A propellant-free foamable aqueous composition capable of forming a stable foam when dispensed from a propellantless finger actuated mechanical pump dispenser and suitable for use as a vaginal or hemorrhoidal wipe comprising:

(a) water;

(b) surfactant which is a combination of polysorbate 20, [triethylamine]
triethanolamine-cocoyl glutamate and disodium cocoamphodiacetate; and

(c) foam stabilizing agent.

NY_MAIN 335801v1